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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,550	11/07/2003	Wichai Cherdshewasart	3884-0115P	8243
2292	7590	01/14/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,550

Applicant(s)

CHERDSHEWASART, WICHAI

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed November 4, 2004 is acknowledged and has been entered. Claims 2 and 3 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being obvious over Pangsrivongse (Rev. Filipina Med. Farm., 1938 - CAPLUS abstract), the admitted state of the art, and the reference entitled "Thailand: Thai Equivalent Viagra Drug Unveiled" (source: Nation - PROMT Newsletter Abstract, March 24, 1999), in view of Pope (GB 785,987).

Pangsrivongse beneficially teaches that the root of *Butea superba* is esteemed as a "rejuvenating drug" in Siam and, further, that active principles were effectively obtained therefrom via alcoholic extraction (see CAPLUS abstract). In addition, as readily admitted by Applicant, the tubers (roots) of *Butea superba* have long been used in the prior art as a raw material for invigorating males in Thailand (see, e.g., page 2, lines 1-3, of the instant spec.).

The PROMT Newsletter Abstract beneficially teaches a potency pill (or pharmaceutical gel or capsule) containing red kwao krua (which, as readily admitted by Applicant is also known as *Butea superba* (see, e.g., page 1, line 13 of the instant specification) which is disclosed as enabling the user to increase sexual potency and as being the Thai equivalent to the drug Viagra (a drug which is extremely well known in the art to be used to effectively treat erectile dysfunction/ malfunction when administered to a male in need thereof).

None of the above references expressly teach particular steps as recited within the currently amended method of using the product-by-process claims (e.g., drying, pulverizing the roots/tubers and/or filtering, concentrating, removing the extract solvent therefrom).

Pope teaches that a preparation from the root of the Siamese plant historically thought to be *Butea superba* enabled an impotent old man to become the father of a new offspring, and that a closely related plant - *Pueraria mirifica* (originally thought to be *Butea superba*) was apparently the actual historic Siamese plant (see, e.g., page 1, line 9 - page 2, line 12). Pope further beneficially teaches a method of making such an extract preparation whereby the roots of the plant are dried, pulverized (powdered), extracted with aqueous methanol or ethanol, and separating the solvent solution - e.g., by filtration - then evaporated (concentrated) to dryness (see, e.g., page 2, line 39 - 87).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat erectile dysfunction/malfunction via administering a pharmaceutically effective amount of an alcoholic extract of *Butea superba* roots/tubers to a male in need thereof, based upon the beneficial teachings provided by the cited references, as well as that which is admittedly well known in the prior art, with respect to the art-recognized Viagra-like rejuvenating invigorating properties of this plant. It would further have been obvious to one of ordinary skill in the art to obtain and utilized an extract preparation from the roots of *Butea superba* using the process steps beneficially taught by Pope based upon the beneficial teachings therein, including that both of the plant species *Butea superba* and *Pueraria mirifica* are very closely related - causing *Butea superba* to be misidentified as *Pueraria mirifica* for numerous years. Accordingly, one of ordinary skill in the art would reasonably expect extract

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preparations from each of these closely related plant species to share similar therapeutic functions - including, e.g., treating erectile dysfunction and/or impotence. The adjustment of particular conventional working conditions (e.g., drying the final product via conventional vacuum-drying, freeze-drying, and/or spray-drying instead of by evaporation - please also note that a product dried in any of these conventional manners would result in final product having the same essential bioactive characteristics and, thus, would not lend patentable distinction thereto) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments as they pertain to the above rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that Pangsrivongse does not disclose or suggest that an extract of *Butea superba* will be able to treat erectile dysfunction, nor does it teach or suggest the claimed method; and that the reference entitled "Thailand: Thai Equivalent Viagra Drug Unveiled" is unaccompanied by experimental data and discloses that it is used to produce more sperm and increase sexual potency, which is not the same as treating erectile dysfunction. However, Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's

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dysfunction.

Applicant's amendment
necessitated

claimed invention fails to patentably distinguish over the state of the art represented by the references. Further, please note that as the title of the PROMT Newsletter Abstract clearly implies, such a red kwao-krua (*Butea superba*) preparation would be useful in an equivalent manner as ViagraTM - which is notoriously well known in the art to be useful for treating erectile dysfunction..

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
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